

Application No. 10/628,787
Amdt. dated November 22, 2005
Reply to Office action of July 22, 2005

Remarks/Arguments

Claims 1-9 stand rejected. New claims 35-40 have been added and find support in the original claims as filed, throughout the specification and, e.g., Example 6-8. Claims 35-40 fall within the same invention as elected claims 1-9, no new fees are required as the total number of claims is less than 3 independent and 20 total after cancellation of claims 10-24.

The claims stand rejected as follows:

Claims 1, 4-9 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. 5,223,420 ('420), which is said to disclose a patch that includes cellular components.

Claims 1, 4-9 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. 5,842,477 ('477), which is said to disclose a patch that includes collagen and fibroblasts.

Claims 1-8 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. 6,596,304 ('304), which is said to disclose collagen I, III and fibroblasts.

Claims 1-8 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 2002/0015724 ('724), which is said to disclose collagen I, III and connective tissue growth factor and/or fibronectin.

Claims 1, 4-8 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 2002/0028243 ('243), which is said to disclose an adhesion prevention barrier with collagen, elastin and fibroblasts.

Claims 1-9 are rejected under 35 U.S.C. § 103(a) as requiring as to the inventorship of the application.

Claims 1-9 are rejected under 35 U.S.C. § 103(a) as being obvious in light of the '032 and '987 patents.

Claims 2 and 3 are rejected under 35 U.S.C. § 103(a) as being obvious in light of the '477 and '032 patents.

Claims 2 and 3 are rejected under 35 U.S.C. § 103(a) as being obvious in light of the '243 and '032 patents.

Claim 9 is rejected under 35 U.S.C. § 103(a) as being obvious in light of any of '420, '304, '724 or '243 in view of the '987 patent.

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Rejections under 35 U.S.C. §102(b) and 35 U.S.C. §102(e).

Test for Anticipation under 35 U.S.C. § 102(b). As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Also, as noted above, the test for anticipation under 35 U.S.C. §102(b) is whether a single reference literally reads on the claim; what the reference broadly teaches is not the issue; any differences between the claimed invention and the reference are sufficient to prevent a 102 rejection. See *Constant v. Advanced Micro-Devices, Inc.*, 7 USPQ2d 1057 (Fed. Cir. 1988).

Each of the 35 U.S.C. §102 rejections is addressed in turn.

Claims 1, 4-9 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. 5,223,420 ('420), which is said to disclose a patch that includes cellular components. The '420 patent fails because it does not include each and every element of the invention as claimed. It is not sufficient to merely find one component of the claimed invention to present a proper 35 U.S.C. §102 rejection. The '420 patent teaches, at most, an elastin containing composition comprising fibronectin and wherein elastin is covalently bound to fibrin monomers. Simply stated, elastin is not collagen. Furthermore, the only mention of collagen in the '420 patent is as an "additive," which by definition is not a substantial component of the composition. Thus, the record is clear that the '420 patent does not show each and every element of claims 1, 4-9 and Applicant, therefore, submits that the rejection of claims 1, 4-9 under 35 U.S.C. §§ 102(b) over the art cited is improper and should be withdrawn.

Claims 1, 4-9 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. 5,842,477 ('477), which is said to disclose a patch that includes: collagen and engineered fibroblasts. The '477 patent fails because it does not include each and every element of the invention as claimed. It is not sufficient to merely find one component of the claimed invention to present a proper 35 U.S.C. §102 rejection. For the same reasons as the '420 patent fails, the '477 patent fails as prior art because, simply stated, cartilage is not collagen. Furthermore, to function, the '477 invention requires the addition of cells (e.g., stromal cells) to the composition. It is not sufficient to conduct a prior art search for the terms in the present application and state that, by their mere presence, the disclosure is prior art. Furthermore, it is improper to use the present disclosure as a "scaffold" to overlay random terms from the art to "engineer" a rejection. The art cited must include each and every element of the claimed invention and that invention must be functional. That is simply not the case for the '477 patent, as it does not use Type I and Type II collagen. Furthermore, the

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invention is clearly designed to "repair" cartilage, that is, to reconstitute its mechanical and physical properties, one of which is adhesion to the adjacent tissue. That is the exact opposite of the present invention.

Thus, the record is clear that the art cited does not show each and every element of claims 1, 4-9 and Applicant, therefore, submits that the rejection of claims 1, 4-9 under 35 U.S.C. §§ 102(b) over the art cited is improper and should be withdrawn.

Claims 1-8 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. 6,596,304 ('304), which is said to disclose collagen I, III and fibroblasts. The '304 patent fails because it does not include each and every element of the invention as claimed. It is not sufficient to merely find one component of the claimed invention to present a proper 35 U.S.C. §102 rejection. The '304 patent fails for the same reasons as cited hereinabove, namely, that the art does not teach each and every element of the claimed invention. In the case of the '304 patent, it clearly fails as prior art because the collagen used is heat denatured, that is, it is not in its natural state. To prepare the patch in the '304 patent the disclosure teaches heat denaturation of the collagen to 40 to 50 degrees centigrade, thereby eliminating its three-dimensional structure. As such, the collagen of the '304 patent is not the same as the acellular collagen claimed herein.

Thus, the record is clear that the art cited does not show each and every element of claims 1-8 and Applicant, therefore, submits that the rejection of claims 1-8 under 35 U.S.C. §§ 102(b) over the art cited is improper and should be withdrawn.

Claims 1-8 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 2002/0015724 ('724), which is said to disclose collagen I, III and connective tissue growth factor and/or fibronectin. The '724 application fails because it does not include each and every element of the invention as claimed. It is not sufficient to merely find one component of the claimed invention to present a proper 35 U.S.C. §102 rejection. The '724 application could not be more different than the claimed invention, as it is meant to cause adhesion. The '724 application discloses a "sealant" or adhesive that are formed by chemically polymerizing the proteins. No such chemical cross-linking occurs in the present invention. Therefore, the '724 patent also fails because it is adhesive and is chemically cross-linked.

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Thus, the record is clear that the art cited does not show each and every element of claims 1-8 and Applicant, therefore, submits that the rejection of claims 1-8 under 35 U.S.C. §§ 102(b) over the art cited is improper and should be withdrawn.

Claims 1, 4-8 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 2002/0028243 ('243), which is said to disclose an adhesion prevention barrier with collagen, elastin and fibroblasts. The '243 patent fails because it does not include each and every element of the invention as claimed. It is not sufficient to merely find one component of the claimed invention to present a proper 35 U.S.C. §102 rejection. The '243 application teaches, at most, the compression of biocompatible protein materials to remove biocompatible used for the manufacture of the item. No such compression is required for the formation of the present invention. The solvents used include water, dimethyl sulfoxide (DMSO), biocompatible alcohols, biocompatible acids, oils and biocompatible glycols, which are removed by compression. In fact, the '243 specification refers as the starting material as "non-cohesive, fluidly-flowable, and/or non self-supporting," [0064] prior to the compression process. As such, it is clear that the mechanical compression of the starting materials as used to deform the components in the '243 application, as the preferred pressure are said to be:

More preferably, the molding device used in the method of the present invention will be capable of applying a pressure of from about 3,000 psi to about 25,000 psi for a time period of from about one minute to about ten minutes. [0067].

Thus, the record is clear that the art cited does not show each and every element of claims 1, 4-8 and Applicant, therefore, submits that the rejection of claims 1, 4-8 under 35 U.S.C. §§ 102(b) over the art cited is improper and should be withdrawn.

Statement of Joint Inventorship under 35 U.S.C. § 103(a)

Claims 1-9 are rejected under 35 U.S.C. § 103(a) as requiring as to the inventorship of the application. Applicant was advised in the Office Action of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a). The present invention only has one inventor, as did the parent application. No such statement is therefore required. The inventor has a duty to assign to the same assignee as the prior application, now U.S. Patent No. 6,599,526.

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Rejections for Obviousness under 35 U.S.C. § 103(a)

To sustain the present rejection of claims 1-9 under 35 U.S.C. § 103(a), a prima facie case of obviousness must be established. MPEP § 2142 provides that to establish a prima facie case of obviousness, the following three basic criteria must be met:

(1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings;

(2) There must be a reasonable expectation of success; and

(3) The prior art references must teach or suggest all the claim limitations.

Furthermore, it would appear by the nature of the "element-type" rejections, that is, the selection of one term from the claim to reach the rejections under 35 U.S.C. § 102(b/e) (above) there exists the potential that hindsight was used to "assemble" the rejections made herein. The current case law makes it clear that the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. See *In re Dembiczak*, 50 USPQ2d, 1614, 1617 (Fed. Cir. 1999). "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight." *Id.*

Each of the 35 U.S.C. § 103(a) rejections is addressed in turn.

Claims 1-9 are rejected under 35 U.S.C. § 103(a) as being obvious in light of the '032 and 6,077,987 patents. To the extent that the rejection includes responses to art cited hereinabove, those arguments are incorporated herein by reference. The Applicant agrees that the '032 patent fails as prior art for the reasons stated in the action. The art further fails to teach, suggest or motivate the full and operative invention because the '987 patent is directed to the use of cells. The present invention is acellular. Therefore, there is no way that the '987 patent, in conjunction with art that fails under 102 and 103 to achieve the present invention. Art that is not prior art, can not be used to "recreate" the present invention based on assumptions of what the Applicants [sic] would "desire." The written art is the sole source that the examiner may use to render a rejection as evidence. The Applicant respectfully request that the examiner point to the exact language in the references that is the

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basis for the "teaching, suggestion or motivation" that serves as the evidence on the record, or respectfully request withdrawal of the rejection.

Thus, the record is clear that the art cited does not show each and every element of claims 1-9 and Applicant, therefore, submits that the rejection of claims 1-9 under 35 U.S.C. §§ 103(a) over the art cited is improper and should be withdrawn.

Claims 2 and 3 are rejected under 35 U.S.C. § 103(a) as being obvious in light of the '477 and '032 patents. To the extent that the rejection includes responses to art cited hereinabove, those arguments are incorporated herein by reference. The Applicant agrees that the '477 and '032 patents fail as prior art for the reasons stated in the action. As regards the '032 patent, again, it is clear that the art taught is the use of a "least partially, thermally denatured," which is no longer collagen. The '477 disclosure includes fibroblasts, therefore there is no way that a skilled artisan could have any expectation to achieve the present invention as nowhere do the references teach, at best, a denatured protein matrix that includes cells. As is well known to even the minimally skilled immunologist; severe, immediate graft versus host disease responses as well as allogeneic responses from the host to the graft would cause the rejection of the graft. As such, the art cited fails to achieve the present invention.

Thus, the record is clear that the art cited does not show each and every element of claims 2 and 3 and Applicant, therefore, submits that the rejection of claims 2 and 3 under 35 U.S.C. §§ 103(a) over the art cited is improper and should be withdrawn.

Claims 2 and 3 are rejected under 35 U.S.C. § 103(a) as being obvious in light of the '243 and '032 patents. To the extent that the rejection includes responses to art cited hereinabove, those arguments are incorporated herein by reference. The Applicant agrees that the '243 and '032 patents fail as prior art for the reasons stated in the action. As regards the '032 patent, again, it is clear that the art taught is the use of a "least partially, thermally denatured," which is no longer collagen. The '243 is not directed to pure collagen, and furthermore, is a mere dried hydrogel. Furthermore, there is nothing in either reference to suggest or motivate the combination and no such reference is quoted in the office action. If such a reference exists in the text of the art cited to combine the references, the Applicant requests that the examiner make of record and place it into evidence or withdraw the rejection.

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Thus, the record is clear that the art cited does not show each and every element of claims 2 and 3 and Applicant, therefore, submits that the rejection of claims 2 and 3 under 35 U.S.C. §§ 103(a) over the art cited is improper and should be withdrawn.

Claim 9 is rejected under 35 U.S.C. § 103(a) as being obvious in light of any of '420, '304, '724 or '243 in view of the '987 patent. To the extent that the rejection includes responses to art cited hereinabove, those arguments are incorporated herein by reference. The Applicant agrees that the '304, '724 or '243 in view of the '987 patents fail as prior art for the reasons stated in the action. This rejection is based solely on the assembly of art based on the present invention. There is not a single, teaching, suggestion or motivation taught in the art cited to combine the reference, much less four (4) references. The Applicant earnestly requests that the exact cites to the language that is used to connect the references be provided at the earliest possible time or that the rejection be withdrawn forthwith. Again, the use of cells in the art is outside the invention as claimed and is therefore not proper art to base a rejection.

Thus, the record is clear that the art cited does not show each and every element of claim 9 and Applicant, therefore, submits that the rejection of claim 9 under 35 U.S.C. §§ 103(a) over the art cited is improper and should be withdrawn.

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Conclusion

In light of the remarks and arguments presented above, Applicant respectfully submits that the claims in the Application are in condition for allowance. Favorable consideration and allowance of the pending claims is therefore respectfully requested.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

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Respectfully submitted,



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